

REMARKS

In view of the above amendments and the following remarks, reconsideration of the outstanding office action is respectfully requested. Pursuant to 37 CFR § 1.121, attached as Appendix A is a Version With Markings to Show Changes Made.

The Office has objected to the drawings under 37 CFR § 1.83(a) asserting that the blanket, blanket having channels, mattress, and mattress pad recited in claims 22-29, 41-50, 70, 77-81, 82-86, and 88 must be shown or the features canceled from the claims. Accordingly, Applicants have submitted a Proposed Amendment to the Drawings which has added Figures 7-9 which show a blanket having channels and apertures, a mattress, and a mattress pad, respectively, and have amended pages 5 and 11 of the specification to include a description and reference numerals relating to these figures. Support for this amendment can be found on page 1, lines 15-17 and claims 22-29, 41-50, 70, 77-86, and 88 of the above-identified patent application. No new matter has been added by this amendment. In view of the foregoing amendments and remarks, the Office is respectfully requested to reconsider and withdraw the objection.

The Office has objected to Figures 1 and 2 for failing to include a legend, such as "Prior Art." Accordingly, Applicants have submitted a Proposed Amendment to the Drawings which includes the legend "Prior Art" on Figures 1 and 2. No new matter has been added. In view of the foregoing amendments and remarks, the Office is respectfully requested to reconsider and withdraw the objection.

The Office has objected to the drawings under 37 CFR § 1.84(p)(4) asserting that the reference character "46" has been used to designate both a display/input unit and a hot reservoir. Accordingly, Applicants have submitted herewith a Proposed Amendment to the Drawings which replaces the reference character "46" with reference character "45" when used to designate the display/input unit in Figures 3, 4, and 6, and have amended pages 6 and 11 of the specification to replace the reference character "46" with reference character "45" when used to designate the display/input unit. No new matter has been added by this amendment. In view of the foregoing amendments and remarks, the Office is respectfully requested to reconsider and withdraw the objection.

The Office has objected to the specification because of the following informality at page 1, line 23: "hypothermia or hypothermia" should be changed to --hypothermia or hyperthermia--. Accordingly, Applicants have amended page 1, line 23 of the specification to read "hypothermia or hyperthermia." No new matter has been added by this amendment. In view of the foregoing amendments and remarks, the Office is respectfully requested to reconsider and withdraw the objection.

The Office has rejected claims 74-76 under 35 U.S.C. § 112, second paragraph for indefiniteness. The Office asserts that the limitation "temperature below the mammal's normal temperature, the mammal's normal temperature, and a temperature above the mammal's normal temperature" is not clear because of what temperature that applicants want to mention. Applicants respectfully traverse the Office's rejection of claims 74-76. In contrast to the Office's position, claims 74-76 clearly recite that the predetermined-desired temperature of the mammal is any one of a temperature below the mammal's normal temperature, the mammal's normal temperature, or a temperature above the mammal's normal temperature. In view of the foregoing remarks, the Office is respectfully requested to reconsider and withdraw the rejection.

The Office has objected to claims 22-29, 41-50, 70, 77-81, 82-86, and 88 as a result of the language "blanket, or mattress, or mattress pad," asserting that the claimed blanket, mattress, or mattress pad should be given a reference numeral in the specification and drawings or the features canceled from the claims. Accordingly, Applicants have submitted a Proposed Amendment to the Drawings which has added Figures 7-9 which show a blanket having channels and apertures, a mattress, and a mattress pad, respectively, and have amended pages 5 and 11 of the specification to include a description and reference numerals relating to these figures. Support for this amendment can be found on page 1, lines 15-17 and claims 22-29, 41-50, 70, 77-86, and 88 of the above-identified patent application. No new matter has been added by this amendment. In view of the foregoing amendments and remarks, the Office is respectfully requested to reconsider and withdraw the objection.

The Office has rejected claims 1-3, 10-12, 20-29, 30-32, 40-56, 63-66, 69, 70, 73-76, and 77-88 under 35 U.S.C. § 102(a) as being anticipated by PCT Publication No. WO

99/44552 to Kushnir ("Kushnir") and has rejected claims 4-9, 13-19, 33-39, 57-62, 67, 68, 71, and 72 under 35 U.S.C. § 103(a) as being unpatentable over Kushnir.

More specifically, the Office asserts that Kushnir teaches a device for delivering a desired medium at certain temperature ranges for temperature management of a mammal including an inlet source for receiving and directing the desired medium to a temperature-control device, a bio-feedback device which measures the mammal's actual temperature and transmits that measurement to the temperature control device, and an outlet source directing the desired medium to manage the temperature of the mammal. The Office also argues that Kushnir discloses that when the actual temperature of the mammal is above a predetermined desired temperature, the temperature control device alters the temperature of the desired medium to a predetermined differential from the actual temperature and when the actual temperature of the mammal is below the predetermined desired temperature, the temperature control device alters the temperature of the desired medium to a pre-set differential from the actual temperature. Moreover, the Office argues that Kushnir discloses that the temperature-control device can alter the temperature of the desired medium at a predetermined rate.

In contrast to the Office's position, Kushnir neither anticipates, suggests, nor discloses "when the actual temperature is above the predetermined-desired temperature; the temperature-control device alters the temperature of the desired medium to a predetermined differential from the actual temperature; and wherein when the actual temperature is below the predetermined-desired temperature, the temperature-control device alters the temperature of the desired medium to a pre-set differential from the actual temperature," as required by claims 1 and 30, "when the actual temperature is above the predetermined-healthy temperature, the temperature-control device alters the temperature of the desired medium to a predetermined differential from the actual temperature; wherein when the actual temperature is below the predetermined-healthy temperature, the temperature-control device alters the temperature of the desired medium to a pre-set differential from the actual temperature; and wherein when the actual temperature is about the predetermined-healthy temperature, the temperature-control device alters the temperature of the desired medium to maintain the actual temperature," as required by claim 10, "when the actual temperature is above the predetermined-desired temperature, the temperature-control device alters the temperature of

the desired medium at a predetermined rate; and wherein when the actual temperature is below the predetermined-desired temperature, the temperature-control device alters the temperature of the desired medium at a predetermined rate,” as required by claim 54, and “when the actual temperature is above the predetermined-desired temperature, the temperature-control device alters the temperature of the mammal at a predetermined rate; and wherein when the actual temperature is below the predetermined-desired temperature, the temperature-control device alters the temperature of the mammal at a predetermined rate,” as required by claim 64.

Moreover, Kushnir neither anticipates, suggests, nor discloses “wherein the temperature-control device alters the temperature of the medium to a predetermined differential, the predetermined differential being limited by a maximum permitted differential throughout a range determined by the user’s actual temperature,” as required by new claims 89 and 111, or “wherein the temperature control device alters the temperature of the medium at a predetermined rate based on the user’s actual temperature,” as required by new claims 102 and 123.

In particular, the Office’s attention is respectfully directed to page 5, line 23 to page 6, line 4 of Kushnir, which discloses that control of the heat exchange properties of the heat exchanger may involve changing “the heat transfer properties between the heat exchanger and the body surface . . . or preferably, by changing the temperature of the heat exchanger, which may either be a reduction in the extent of heating or cooling, halting the heating or cooling operation, or reversing the heating or cooling operation.” Moreover, the Office’s attention is respectfully directed to page 10, lines 6-12 of Kushnir, which discloses that the user interface of the device may include “control means allowing selective operation of the system in either an automatic mode, namely in a mode permitting both cooling or heating depending on the direction or deviation of the aBCT [actual body core temperature] from the dBCT [desired body core temperature] . . . a heat only mode or a cool only mode.” Further, the Office’s attention is respectfully directed to page 16, lines 5-7, which discloses “two flow control valves 106 and 107, for selectively transferring return fluid to or drawing fluid from one of the two reservoirs.”

Thus, in contrast to the Office's position, Kushnir neither discloses nor suggests alteration of the temperature of the desired medium to a predetermined or pre-set differential, from the actual temperature of the mammal, as required by claims 1, 20, 30, and their dependent claims. In particular, as used herein, alteration of the temperature of the desired medium to a predetermined or pre-set differential from the actual temperature of the mammal involves altering the temperature within a predetermined temperature range limited by a maximum permitted differential determined by the user's actual temperature. More specifically, as set forth at page 5, lines 30-33 of the specification, the devices of the present invention control the temperature of the desired medium "in a predetermined ratio to the temperature of the mammal." In addition, as set forth at page 8, lines 2-7 of the specification, the amount of hot and cold medium mixed in the manifold of the devices of the present invention "depends on the temperature of the mammal" and, optionally, "the temperature of the Mixed Medium in the Object." Kushnir neither discloses nor suggests altering the temperature of the medium within a predetermined temperature range limited by a maximum permitted differential that is determined by the user's actual temperature, and, therefore, neither discloses nor suggests altering the temperature of the medium to a predetermined or pre-set differential from the actual temperature.

Moreover, in contrast to the Office's position, Kushnir neither discloses nor suggest alteration of the temperature of the desired medium or the mammal at a predetermined rate, as required by claims 54, 64, new claim 102, new claim 123, and their dependent claims. Further, Kushnir neither discloses nor suggests alteration of the temperature of the medium to a predetermined differential, the predetermined differential being limited by a maximum permitted differential throughout a range determined by the user's actual temperature, as required by new claims 89, 111, and their dependent claims.

Rather, Kushnir simply discloses the use of flow control valves for transferring return fluid to or drawing fluid from either hot or cold reservoirs to control of the heat exchange properties of the heat exchanger, without any disclosure or suggestion relating to control of the alteration of the temperature of the desired medium or mammal to a predetermined or pre-set differential or at a predetermined rate. The only disclosure in Kushnir regarding any control over the alteration of the temperature of the desired medium is

at page 10, lines 13-16, where Kushnir discloses that heating is limited so that the “temperature at the surface of the heat exchanger . . . will not exceed maximum temperature . . . and not to fall below a minimum temperature.”

The alteration of the temperature of the desired medium to a predetermined or pre-set differential from the actual temperature of the mammal which is limited by a maximum permitted differential throughout a range determined by the user's actual temperature or at a predetermined rate, as required by the claims of the present invention, eliminates the discomfort caused to a user of prior art devices which apply the warmest or coldest medium available to the user when adjusting the temperature of the medium. In particular, the application of the warmest or coldest medium available in prior art devices may occur when the device initially attempts to adjust the temperature of the medium based on a large temperature difference between the actual temperature of the user and the desired temperature of the user, or when the difference between the temperature of the medium and the desired temperature of the user is not large, but exists for a long period of time. This considerable difference in the temperature of the medium and the actual temperature of the user can cause significant discomfort (e.g., a feeling of burning or freezing on the skin). In contrast, in the devices of the present invention, the temperature of the medium applied to the user only differs from the actual temperature of the user by a predetermined amount within a predetermined range, so as not to cause any discomfort to the user.

Accordingly, in view of the foregoing amendments and remarks, the Office is respectfully requested to reconsider and withdraw the rejection of claims 1, 10, 30, 54, and 64. Since claims 2-9, 20, 22, 24, 26, 28, 46, 49, 51, and 74 depend from and contain the limitations of claim 1, claims 11-19, 21, 23, 25, 27, 29, 45, 48, and 52 depend from and contain the limitations of claim 10, claims 31-44, 47, 50, 53, and 76 depend from and contain the limitations of claim 30, claims 55-63 and 82-88 depend from and contain the limitations of claim 54, and claims 65-73, 75, and 77-81 depend from and contain the limitations of claim 64, they are distinguishable over the cited reference and are patentable in the same manner as claims 1, 10, 30, 54, and 64.

In view of the foregoing amendments and remarks, it is believed that this application is in condition for allowance. A notice to this effect is respectfully requested. Should any further questions arise concerning this application, the Examiner is invited to call Applicants' attorney at the number listed below.

Respectfully submitted,

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Appendix A**Version With Markings to Show Changes Made**

In reference to the amendments made herein to the specification, additions appear as underlined text, while deletions appear as bracketed text, as indicated below:

In The Specification:

At page 1, lines 20-31:

The object of the MEDI-THERM II® hypo/hyperthermia machine is to stabilize a patient who is experiencing hypothermia or hyperthermia or, in some instances, to actively cause hypothermia or [hypothermia] hyperthermia as therapy. To understand the MEDI-THERM II® device, we will revert to Figure 1 (prior art) which is a flow diagram of how the MEDI-THERM II® device distributes water to and from an Object. The liquid medium enters MEDI-THERM II® device through return inlet 52. From return inlet 52, the liquid medium traverses through a first conduit 30 to a first solenoid valve 32 for cold liquid medium or a second solenoid valve 34 for warm liquid medium.

At page 6, lines 6-14:

One embodiment of the present invention is illustrated in Figure 3. This embodiment relates to a liquid medium delivery device 10. The exterior of the device 10 has at least one supply outlet 14, a kill switch 444 which can shut down the entire device 10 by conventional interconnections between the various components of device 10, a display/input unit [46] 45, at least one outlet conduit 18, a return conduit 50, a return inlet 52, and an Object 16.

At page 11, lines 9-18:

In one embodiment of the present invention, the values for the predetermined differential, the pre-set differential, the predetermined-maximum temperature, the Set Point Body Temperature, and the pre-selected differential can be entered into the processing unit 90

through the display/input unit [46] 45 by a user. Alternatively, these values can be pre-programmed and activated by merely striking a desired switch. Device 10 when using these values decrease the discomfortness to the patient 20.